

January 27, 2003

United States Department of Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-03

Marketing and Regulatory Programs

Subject:

Temporary Change in Services Provided by the

Center for Veterinary Biologics

Animal and Plant Health Inspection Service

To: Biologics Licensees, Permittees, and Applicants

Veterinary Services Management Team Directors, Center for Veterinary Biologics

Veterinary Services

Center for Veterinary Biologics Suite 104 510 South 17th Street Ames, IA 50010 (515) 232-5785 FAX (515) 232-7120

The recent outbreak of Exotic Newcastle Disease in California and Nevada has resulted in diversion of the Center for Veterinary Biologics' (CVB) resources to California and locally for the purpose of management of this animal health emergency. See http://www.aphis.usda.gov/lpa/issues/enc/exoticnc.html for more information on the outbreak of Exotic Newcastle Disease in the United States. In order to assist with the emergency, the CVB will be changing practices to provide specialized expertise for emergency response functions, while balancing these priorities against our role of regulating veterinary biologics. The CVB will retain mission-critical activities in all program areas (e.g., submission review, testing, inspection, compliance); however, staffing shortages will impact response time.

Biologics manufacturers are requested to provide notice to CVB of submissions and activities of critical importance including review, testing, and prelicensing. With biologics manufacturers' support, available resources can be directed to meet critical needs.

All requests for priority of critically important or time-sensitive activities are to be directed to Dr. Louise Henderson, Center for Veterinary Biologics, 510 South 17th Street, Suite 104, Ames, IA 50010, who will collect the information and assign coverage as resources permit. Please continue to send routine submissions to your regular program person.

We appreciate your patience during this animal health emergency and plan to resume our normal delivery of service at the earliest possible date.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr. Director Center for Veterinary Biologics

